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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,153	09/13/2000	Matthew A. Howard III	UIOWA-8PAD1	7887

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EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/661,153	HOWARD III, MATTHEW A.	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10,12-15,41-44,52,53,56,57,59-64 and 66-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *63,64,67-70,85 and 88* is/are allowed.

6)☒ Claim(s) *8-10,12,41,43,52,53,57,59,60,62,71,73,74,77,79,83,86,89,92 and 94* is/are rejected.

7)☒ Claim(s) *13-15,42,44,56,61,66,72,75,76,78,80-82,84,87,90,91 and 93* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The objection to the specification is withdrawn in light of the amendment dated 10/19/04.

Claim Objections

Claim 66 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 66 contains the same subject matter as is stated in claim 63.

The objection to claims 8,12-14,41,80 and 82-83 is withdrawn in light of the amendment dated 10/19/04.

Appropriate correction is required.

Drawings

The objection to the drawings is withdrawn in light of the amendment dated 10/19/04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (US pat# 5,531,679). Schulman discloses a fluidic infusion system for a catheter that includes a plurality of non-coaxial infusion catheters (12'), a macrocatheter (10) for housing the infusion catheters, a pump (P1) and a manifold (26'). See figure 6. The device further includes at least one electrode (27) which is configured (in that electrodes are metal) to sense electrical activity of the brain. See 9:42.

Schulman meets the claim limitations as described above but fails to teach the plurality of non-coaxial infusion catheters being microinfusion catheters. However, at the time of the invention, it would have been obvious to make the device of Schulman on a small scale. Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Additionally, the motivation to make the device of Schulman a very small device in size or caliber would have been in order to accommodate much smaller vessels such as arterioles.

Claims 8,12,41,52-53,57,62,71,73,77,79,92 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al (US pat# 5,772,629). Kaplan discloses a plurality of non-coaxial infusion catheters (126), a macrocatheter (GC) for housing the infusion catheters, a pump (see 7:45) and a manifold (114). See figures 1-2 and 11. The device further includes a drug supply line (116) and infusion ports along the length of the catheters (128). A syringe (see 7:45) is capable of pumping at a variable rate.

Kaplan meets the claim limitations as described above but fails to teach the plurality of non-coaxial infusion catheters being microinfusion catheters. However, at the time of the invention, it would have been obvious to make the device of Kaplan on a small scale. Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Additionally, the motivation to make the device of Kaplan a very small device in size or caliber would have been in order to accommodate much smaller vessels such as arterioles.

Regarding claim 41 and 62, Kaplan meets the claim limitations as described above but fails to include that the drug is an appetite controlling drug. However, at the time of the invention, it would have been obvious to incorporate any drug, including an appetite controlling drug, into the invention of Kaplan. Any drug would meet the purpose of the invention of Kaplan, i.e. a device designed to introduce a drug into a target site within the body. Hence, it would be obvious to incorporate any drug, including an appetite suppressing drug, into the invention of Kaplan since the invention is designed for that purpose.

Claims 9-10,43,59,60,74,83 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view of Scheinman et al (US Pat# 5,429,131). Kaplan meets the claim limitations as described above but fails to include the macrocatheter having a magnet or the device having monitoring electrodes.

However, Scheinman discloses the teaching of using sensing electrodes and magnetized electrodes for sensing the electrical impulses in the heart and for tracking the positioning of the catheter within the heart. The sensing electrodes provide a map of the heart.

At the time of the invention, it would have been obvious to incorporate the electrodes for both mapping and tracking into the invention of Kaplan. Both devices are analogous in the art and therefore a combination is proper. Additionally, both devices are designed for cardiac use and treatment. Furthermore, the motivation for incorporating would have been in order to provide the device of Kaplan with an enhanced method of device positioning within the body to easily and accurately carry out the procedure thereby enhancing the overall safety of the patient.

Allowable Subject Matter

Claims 63,64,67-70,85 and 88 are allowed.

Claims 13-15,42,44,56,61,66,72,75,76,78,80-82,84,87,90,91 and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: the allowability of the independent claims above is based on the combination of all the limitations within each claim.

Regarding claims 63 and 88, the prior art fails to teach a drug infusion device having the combination of a plurality of non-coaxial microinfusion catheters where at least one microinfusion catheter comprises a plurality of individually controllable drug delivery ports disposed along a length of the at least one microinfusion catheter and a macrocatheter configured to house the plurality of microinfusion catheters.

Regarding claim 85, the prior art fails to teach a drug infusion device having the combination of a plurality of non-coaxial microinfusion catheters where at least one microinfusion catheter comprises a plurality of individually controllable drug delivery ports disposed along a length of the at least one microinfusion catheter, a pump configured to controllably supply a drug to the plurality of microinfusion catheters and a manifold configured to convey the drug from the pump to the plurality of microinfusion catheters.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

Applicant's arguments filed 10/19/04 have been fully considered but they are not persuasive.

Regarding claim 86, applicant argues that Schulman does not disclose at least one electrode configured to sense electrical activity of the hypothalamus. See Schulman 9:42 for disclosure of an electrode. However, as detailed above the fact the prior art device has a sensing electrode reads on the limitation of "at least one electrode configured to sense electrical activity of the hypothalamus". The electrode itself can be used for any function and therefore is considered configured for any function. Whether the electrode is used for sensing or stimulation is a function of the electrical system/ processor/circuitry connected to the electrode and not the electrode itself. Hence, any electrode (on it own) is configured for any function minus any

further limitation as to for example, means for sensing that would incorporate more than just the electrode.

Regarding applicant's arguments that Schulman does not disclose a device configured to infuse the drug into a hypothalamus of a patient, applicant is reminded that the present claim is a device claim and functional recitations are given limited patentable weight. The fact that the prior art device is an instrument for entry into blood vessels renders it configured to be used in any vascular, tubular, cavity, sinus or any other area within the patient's body in which it could be inserted.

Regarding applicant's arguments to the rejection of the claims in view of Kaplan, applicant is referred to the drawings of the prior art. The prior art in figures 8 and 9 show apertures that are spaced longitudinally from one another. Each port occupies a different longitudinal site on the axis of the catheter. It is this longitudinal spacing that reads on "each drug delivery port of the plurality of drug delivery ports is configured to deliver a drug to a separate site within the hypothalamus".

Regarding applicant's arguments that Kaplan does not disclose a device configured to infuse the drug into a hypothalamus of a patient, applicant is reminded that the present claim is a device claim and functional recitations are given limited patentable weight. The fact that the prior art device is an instrument for entry into blood vessels renders it configured to be used in any vascular, tubular, cavity, sinus or any other area within the patient's body in which it could be inserted.

Regarding applicant's argument that Kaplan does not teach a plurality of microcatheters moveably disposed within a macrocatheter and configured to extend beyond an end of the

macrocatheter. The macrocatheter in the above rejection is identified as the guiding catheter (GC) of the prior art. The microcatheters move and extend beyond this macrocatheter during insertion into the body. See 8:27-65.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams CSW.
January 7, 2005

NICHOLAS D. LUCCHESI
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